Cape Apothecary, Inc.
1384 Cape St. Clair Road
Annapolis, Maryland 21409
Permit No. P01639

Date: Feb. 28, 2017

Mitra Gavgani, Pharm. D., President
Maryland State Board of Pharmacy
4201 Patterson Avenue
Baltimore, Maryland 21215-2254

Re: Permanent Surrender of pharmacy permit
Permit No. P01639
Case No. PI-16-067

Dear Ms. Gavgani and Members of the Board,

I agree to voluntarily and permanently **SURRENDER** the pharmacy permit of the pharmacy I own, Cape Apothecary, Inc. (a.k.a. Cape Drugs) in the State of Maryland, permit number **P01639,** to the Maryland Board of Pharmacy (the "Board").[1] I understand that Cape Apothecary, Inc. (the "Respondent-Pharmacy") may not operate a pharmacy, with or without compensation, as it is defined in the Maryland Pharmacy Practice Act (the "Act"), Md. Code Ann., Health Occ. ("HO") § 12-101 *et seq.* and the Board's regulations, Code Regs. Md. ("COMAR") § 10.34.01 *et seq.* In other words, as of the effective date of this Letter of Surrender, I understand that Cape Apothecary Inc. is in the same position as an entity which does not hold a pharmacy permit. I understand that this Letter of Surrender shall become a **PUBLIC** document and shall become effective on the date of the Board's acceptance of this Letter of Surrender as a **FINAL ORDER** of the Board. I agree that this letter may be released or published by the Board as a final decision and order under the Public Information Act, Md. Code Ann., Gen. Prov., §§ 4-101, *et seq.* (2014).

My decision to surrender my pharmacy permit in the State of Maryland has been prompted by an investigation of the pharmacy's permit by the Board and the Office of the Attorney General and resulting charges under the Act. I wish to make it clear that I have voluntarily, knowingly and freely chosen to submit this Permanent Letter of Surrender. I acknowledge that the Office of the Attorney General has legally sufficient evidence to prove by a preponderance of the evidence at an administrative hearing that I violated the provisions of the Act and corresponding regulations as detailed herein. However, Respondent-Pharmacy makes no admission of liability with respect to the charges alleged.

On August 12, 2016, the Food and Drug Administration ("FDA") issued a warning letter to Respondent-Pharmacy after having conducted inspections of the pharmacy from September

[1] This Letter of Surrender in no way affects the pharmacy license of Thomas Wilson, P.D.

21, 2015, to October 7, 2015. The FDA's letter noted several issues with compounded drugs prepared by the pharmacy, unapproved new drug products, misbranded drug products, and adulterated drug products. The warning letter can be found on the FDA's website at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm516594.htm.

On November 6, 2015, the Respondent-Pharmacy's owner provided a written response to the FDA inspection, which he voluntarily shared with the Board, and admitted the following shortcomings:

a. The Respondent-Pharmacy did not conduct sterility and endotoxin testing on all sterile drug products produced by the Respondent-Pharmacy;
b. The Respondent-Pharmacy was not equipped with a calibrator and qualification thermometer to ensure the quality of sterilization completed by the autoclave;
c. The Respondent-Pharmacy failed to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch had been already distributed.

At some point prior to January 14, 2016, the Respondent-Pharmacy voluntarily agreed to cease all sterile compounding production for an unspecified period of time. In addition, the Respondent-Pharmacy worked with the FDA to recall all aseptically filled products compounded in the 90 days prior to the inspection. The Respondent-Pharmacy provided the Board with a list of these recalls for the period of July -- November 2015, and it included approximately 125 prescriptions.

Based upon the Board's review of this information and environmental samples taken during the FDA inspection, as well as inspection documents, the Board retained an expert pharmacist to opine on the Respondent-Pharmacy's sterile compounding practice. The Board expert opined that the Respondent-Pharmacy violated the standards of practice for sterile compounding in the Maryland Pharmacy Act and corresponding Maryland regulations, which are based on USP 797 Standards. Specifically, the expert opined that the Respondent-Pharmacy and its staff:

a. Failed to adequately address training or provide an appropriate Policy and Procedure Manual for the facility;
b. Failed to properly gown and garb and to use sterile gloves and equipment while setting up or performing procedures;
c. Failed to adequately ensure that standards for assurance of sterility were met;
d. Failed to adequately ensure that standards for laboratory testing were met;
e. Failed to have a systematic and thorough process for end product testing for sterility or stability;
f. Failed to adequately ensure that standards for equipment cleaning, disinfection, and sterilization were met;
g. Failed to adequately ensure that standards for training and observation of personnel were observed;
h. Failed to adequately ensure that standards for calibration of equipment and for

monitoring environmental conditions were met;

i. Failed to adequately ensure that the pharmacy's air handling equipment was adequate;
j. Failed to adequately ensure that the quality assurance process was adequate to evaluate failures in testing results;
k. Failed to conduct a thorough analysis of any discrepancies or product failures; and
l. Failed to adequately ensure that there was an adequate testing process to ensure that all products maintained potency at all times.

The expert noted that failure of any procedure related to testing of the environment, equipment use, procedures for sterilization, calibration, and preventive maintenance of equipment has the potential to result in end product contamination. As an example, the expert noted that the end product testing by an external laboratory on October 27, 2015 demonstrated that some of the products were sub-potent at 85%, which is less than the 90% to 110 % USP potency requirement. The expert noted that "the objective nature of testing equipment is intended to provide a reliable assessment that prior steps provide the necessary patient safety. Any equipment that is not rigorously and regularly tested would provide a false sense of security that would compromise patient protection." The expert opined that the Respondent-Pharmacy did not have a systematic and thorough process for end product testing for sterility or stability. The expert noted that "when the pharmacy began to compound products using non-sterile components and products that were not manufactured specifically for use as sterile compounds for injection or installation, the degree of process control and testing increased exponentially." The fact that products were compounded without adequate end product testing is a significant issue for patient safety.

According to the expert:

> The level of risk of the products produced by the pharmacy requires that testing be conducted to confirm that all final products are not only sterile but that no sterile toxic breakdown products of living organisms (endotoxins) were present. The response from the pharmacy owner confirmed that the testing was not being conducted, questioned the need for the testing and took the position that the requirement was 'too costly.'

Further, this process "is only validated and proved to be sufficiently rigorous when there is end product testing carried out to an adequate level. The pharmacy did not provide an adequate proof of end product testing." More critical was the Respondent-Pharmacy's failure to conduct a thorough analysis of any discrepancies or product failures. The expert noted that

> each failure is an opportunity to analyze existing procedures, develop new approaches to product preparation and retrain and observe staff as they perform the compounding process. This process was not part of a systematic plan of operations in any instance at the Respondent-Pharmacy. [Although] it may not appear to be operationally feasible or cost effective to test batches of product to fully ensure that the resultant product meets standards for sterility and equally importantly, standards for stability, ... this action is essential for any

compounding facility to perform.

The expert also questioned whether it might be feasible to bring the facility into compliance with USP 797 clean room requirements, noting that based on the information in the inspection report, "the facility was very likely placed in an existing space without a full assessment of the air exchange and handling requirements for a USP 797 compliant clean room. The changes required to bring the facility into compliance may not be feasible in the existing space without significant structural changes and the addition of new air handling devices."

In addition, the expert noted that "the documentation confirmed that the cleaning products did not provide a complete range of safety from microbiological contamination and there is no confirmation that the testing of the clean room area was properly conducted."

On June 21, 2016, the Board performed an unannounced annual inspection of the Respondent-Pharmacy, during which the following deficiencies and/or concerns were noted:

a. Food and medications were stored side-by-side in the freezer.
b. There was no thermometer in the freezer.
c. The Respondent-Pharmacy compounds non-sterile bulk non-patient specific products for surgery centers which are otherwise commercially available.
d. The Respondent-Pharmacy only fills prescriptions for cash and does not accept insurance.
e. The Respondent-Pharmacy's staff's annual education on preventing medication errors was outdated.
f. The generic manufacturer of medications was missing from prescription labels.

On or about July 7, 2016, the Board received a complaint alleging that the Respondent-Pharmacy was delivering prescription drugs into Virginia on an expired non-resident pharmacy license. The Virginia Board of Pharmacy confirmed that the Respondent-Pharmacy's non-resident pharmacy license had expired on April 30, 2015. Based upon this complaint, the Board initiated additional investigation of the Respondent-Pharmacy. During the course of its investigation, the Board noted that the previously referenced establishment inspection report completed by the FDA on September 21 - October 7, 2015 indicated stated that: "According to [Thomas Wilson's son], Pharmacist, approximately 2% of products are shipped outside of Maryland. The majority [of these] are shipped to [the] Washington, D.C. and Virginia area."[2]

On August 19, 2016, the Board performed a follow-up inspection from its June 21, 2016 inspection. During this inspection, the following observations were made:

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[2] This person is not a licensed pharmacist in Maryland. He is, in fact, a registered pharmacy technician who was originally registered on November 30, 2009. However, throughout FDA's report, Andrew Wilson is listed as a pharmacist who is "responsible for purchasing supplies including over-the-counter drug products." The report also states that he "reviews laboratory results" and "has the duty, power and responsibility, and authority to prevent, detect, and correct violations in this firm." The Respondent-Pharmacy's response letter to the FDA failed to correctly identify Mr. Wilson's son as a pharmacy technician and not as a pharmacist.

a. A dispensing report provided by the Respondent-Pharmacy for prescriptions filled and dispensed into Virginia between April 20, 2015 and August 19, 2016 indicated that 385 prescriptions with a total price of $30,773.34 were dispensed into Virginia during that period.
b. A medication disposal box was located outside of the pharmacy dispensing area. Although the pharmacist working during the time of the inspection indicated that the pharmacy does not take back any controlled substances, over-the-counter medications or medications containing needles, it was unclear how this could be monitored since the box was outside of the dispensing area. Board staff verified that the Respondent-Pharmacy is not registered with the DEA as a retail collector.
c. The pharmacist on duty during the inspection indicated that the Respondent-Pharmacy compounds BLT (Benzocaine/Lidocaine/Tetracaine)[3] for some patient specific and office uses. A dispensing report provided by the Respondent-Pharmacy for BLT for the period between January 1, 2014 and August 19, 2016 indicated that the Respondent-Pharmacy's compounding logs do not have patient identifiers or prescriber names. The logs only contain the medication name and lot number for the medications being compounded, not patient names or prescription numbers. Also, the Board's inspector noticed several prescription numbers that were repeated throughout the dispensing report with different dispensing dates.
d. The Respondent-Pharmacy prepares cocaine solution that is otherwise commercially available for doctors' offices and surgery centers (i.e. for non-patient specific use). The prescriber's office completes a DEA 222 form[4] for the medication and sends it to the Respondent-Pharmacy, and then the Respondent-Pharmacy will sign the cocaine out of their perpetual inventory and deliver it to the prescriber's offices. The Board inspector requested copies of DEA 222 forms and invoices from January 1, 2014 -- June 28, 2016, but the Respondent-Pharmacy was only able to provide them for five (5) dates within that time period despite evidence that the Respondent-Pharmacy compounded the cocaine solution more than five (5) times during the relevant period.

Thereafter, the Respondent-Pharmacy provided to the Board a dispensing report for all products dispensed from January 1, 2014 through August 19, 2016. The Board's review of this report revealed the following:

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a. The total amount of products distributed totaled approximately $143,569.37, which is greater than 5% of the Respondent-Pharmacy's dispensing total of $2,340,890.65.[5] (5% of $2,340,890.65 = $117,044.53.) The Respondent-

[3] BLT is a topical cream used for pain relief in surgery centers.
[4] A DEA 222 form is an ordering form for ordering CII medications.
[5] A breakdown by year also indicates distribution sales greater than 5% of total sales per year. Section 12-6C-01(v)(2) of the Wholesale Drug Distribution and Permitting Act provides that the term "Wholesale distributor" includes: ... (xii) A pharmacy that conducts wholesale distribution, if the wholesale distribution business accounts

Pharmacy does not hold a wholesale distributor permit.

b. The Respondent-Pharmacy dispensed at least 20 different medications for non-patient specific compounded products for office use to doctors' offices and surgery centers in violation of COMAR 10.34.04 and 21 USCA § 353a, which requires compounded drugs to be prepared pursuant to a patient-specific prescription.

The Respondent-Pharmacy also distributed at least 19 different commercially available FDA-approved products to doctors' offices and surgery centers for office use in violation of 21 USCA § 353a.(b)(1)(D)[6] and thus § 12-409(3) of the Act.

By charging documents dated July 26, 2016 and January 20, 2017, I was notified that based on the foregoing facts, the Board has sufficient evidence to find that Cape Apothecary, Inc. has violated the Pharmacy Practice Act, specifically HO §§ 12-403(c) (1) ("Shall be operated in compliance with the law and with the rules and regulations of the Board"); (2) ("Shall be located and equipped so that the pharmacy may be operated without endangering the public health or safety"); (11) ("(i) Shall maintain at all times the minimum professional and technical equipment and sanitary appliances that are necessary in a pharmacy: 1. To prepare and dispense prescriptions properly; and 2. To otherwise operate a pharmacy; and (ii) Shall: 1. Be equipped with the minimum equipment and appliances specified by the Board under this section; and 2. Be kept in a clean and orderly manner"); (12) ("Shall store all prescriptions or nonprescription drugs or devices properly and safely subject to the rules and regulations adopted by the Board ...."); (19) ("May not allow an unauthorized individual to represent that the individual is a pharmacist..."); and (21) ("Shall dispense or dispose of prescription drugs or medical supplies in accordance with Title 15, Subtitle 6 of the Health-General Article [Prescription Drug Repository Program]"). The Respondent-Pharmacy was also charged with violating several provisions of the Board's regulations at COMAR 10.34.19 (Sterile Pharmaceutical Compounding) pertaining to minimum facility requirements for equipment, minimum requirements for policies and procedures, attire, training of staff, patient and caregiver, and quality assurance. Lastly, the Respondent Pharmacy was charged with violating COMAR 10.34.26 (Patient Safety Improvement) as it pertains to pharmacy staff education and COMAR 10.34.37 (Engaging in wholesale drug distribution in excess of 5% of total sales.)

I understand that by executing this Permanent Letter of Surrender I am waiving any right to contest any charges that would issue from the Board's investigative findings and its vote to issue charges in a formal evidentiary hearing at which I would have had the right to counsel, to confront witnesses, to give testimony, to call witnesses on my own behalf and all other substantive and procedural protections provided by law, including the right to appeal.

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for more than 5% of the pharmacy's annual sales.

[6] 21 USCA § 353a.(b)(1)(D) provides that a pharmacist may not compound "regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product."

I understand that the Board will advise the Association of State Boards of Pharmacy, the National Practitioner's Data Bank, and the HealthCare Integrity Data Bank, and any other required entities of this Permanent Letter of Surrender, and in response to any inquiry, will advise that Cape Apothecary, Inc. has surrendered its license in lieu of disciplinary action under the Act as a resolution of the matters pending against it. I also understand that, in the event that Cape Apothecary, Inc. would apply for licensure in any form in any other state or jurisdiction, that this Letter of Surrender, and all underlying documents, may be released or published by the Board to the same extent as a Final Order that would result from disciplinary action pursuant to Md. Code Ann., State Gov't § 10-611 *et seq.* (2014 Repl. Vol.). Finally, I understand that this Letter of Surrender is considered a disciplinary action by the Board.

I acknowledge that I have provided the Board with all paper copies of the Respondent-Pharmacy's permit, including any renewal certificates or wallet-sized renewal cards.

I acknowledge that I may not rescind this Permanent Letter of Surrender in part or in its entirety for any reason whatsoever. Finally, I wish to make clear that I have had the opportunity to consult with an attorney before signing this Permanent Letter of Surrender. I understand both the nature of the Board's actions and this Permanent Letter of Surrender fully. I acknowledge that I understand and comprehend the language, meaning and terms and effect of this Permanent Letter of Surrender. I make this decision knowingly and voluntarily.

Lastly, Cape Apothecary, Inc. agrees to pay a fine in the amount of $10,000 to the Maryland Board of Pharmacy in certified funds in conjunction with submitting this Permanent Letter of Surrender.

Sincerely,

Thomas J. Wilson, PharmD.

Thomas Wilson, P. D.
Owner, Cape Apothecary, Inc.

NOTARY SEAL

STATE OF Maryland
CITY/COUNTY:

I HEREBY CERTIFY that on this 28th day of February, 2017, before me, a Notary Public of the State and City/County aforesaid personally appeared Thomas Wilson, P.D. on behalf of Cape Apothecary, Inc. and declared and affirmed under the penalties of perjury that

signing the foregoing Permanent Letter of Surrender was his voluntary act and deed.

Notary Public

ACCEPTANCE

On behalf of the Maryland Board of Pharmacy, on this 1st day of March, 2017, I accept Cape Apothecary, Inc's PERMANENT **PUBLIC SURRENDER** of its pharmacy permit in the State of Maryland.

Mitra Gavgani, Pharm..D., President Chair
Maryland Board of Pharmacy